K012469 S1
page 1 of 2

DEC 0 3 2001

BIOMET INC
CORPORATE HEADQUARTERS

SUMMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:
Arthrotek, Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Establishment Registration No.: 1825034

Contact Person:
Sara B. Shultz
Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (219) 267-6639
FAX: (219) 372-1683

Proprietary Name: Resorbable No Profile Screw and Washer

Common or Usual Name: resorbable screw and washer

Classification Name:
Screw, Fixation, Bone, Non-spinal, Non-metallic (888.3040)
Washer, Bolt Nut, Non-spinal, Non-metallic (888.3030)

Device Product Code: 87HWC and HTN

Legally Marketed Devices To Which Substantial Equivalence is Claimed:
Arthrotek Interference Screw (Biomet, Inc., K982497), Harpoon Suture Anchor (Biomet, Inc., K943806/K973775), Sutureless Anchor (Innovasive Devices, K984490), EndoPearl™ with Threader (Linvatec Corp., K993339)

Indications for Use: The Resorbable No Profile Screw and Washer is indicated for the following procedures:

1. ACL and PCL reconstruction
2. Medial collateral ligament repair
3. Lateral collateral ligament repair
4. Posterior oblique ligament repair
5. Iliotibial band tenodesis reconstruction
6. Patellar ligament and tendon repair

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

BIOMET INC
CORPORATE HEADQUARTERS

This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

Device Description: The Resorbable No Profile Screw and Washer consists of a resorbable 6.5 mm screw that varies in length from 25 mm to 55 mm (5 mm increments) and a 18 mm diameter washer. This device is comprised of a PLLA/PGA copolymer.

The device was designed to be used in conjunction with marketed devices such as resorbable or allograft interference screws in ACL reconstruction. The purpose of this back-up fixation will be to provide additional fixation strength in instances of questionable bone quality.

Summary of Technologies: The Resorbable No Profile Screw and Washer technological characteristics (materials, design, sizes, and indications) are similar to or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Biomet Manufacturing, Corporation
c/o Ms. Sara B. Shultz
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K012469
Trade/Device Name: Resorbable No Profile Screw and Washer
Regulation Number: 888.3040 and 888.3030
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener and Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HWC and HTN
Dated: October 24, 2001
Received: October 25, 2001

Dear Ms. Shultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

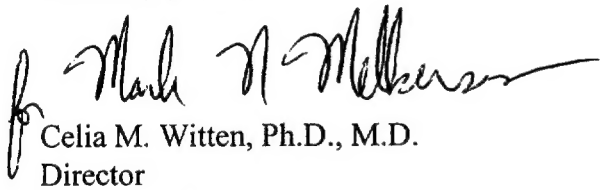
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listingPage (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012469 51

510(k) NUMBER (IF KNOWN): K012469

DEVICE NAME: Resorbable No Profile Screw and Washer

INDICATIONS FOR USE:

The Resorbable No Profile Screw and Washer is indicated for the following procedures:

1. ACL and PCL reconstruction
2. Medial collateral ligament repair
3. Lateral collateral ligament repair
4. Posterior oblique ligament repair
5. Iliotibial band tenodesis reconstruction
6. Patellar ligament and tendon repair

This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012469